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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,056

08/18/2003

Richard Diana

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26389

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EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/643,056	Applicant(s) DIANA, RICHARD	
	Examiner Manuj Agarwal	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 18-20, 25, 26, 32, 34, 35 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-17, 21-24, 27-31, 33 and 36-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following informalities: The last line of page 7 that continues into page 8 is an incomplete sentence.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 8-13, 28, 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Copeland et al (US 4,149,529).**

Regarding claim 1, Copeland discloses therapeutic pad comprising a bladder 22 having an inlet port 25 disposed at the distal portion of the bladder and an outlet port 25 disposed at the proximal portion of the bladder. A fastener 27 is provided, as is a pump 68 (col. 4, lns 40-44). The liquid provided to the inlet port will inherently flow toward the outlet port of the therapeutic pad producing a pressure gradient.

Regarding claims 5 and 6, the bladder must be sealed around the periphery in order to prevent the fluid from escaping. When the fluid hits these sealed portions, it is directed to flow toward the outlet which is generally aligned with the direction of the user's lymph flow.

Regarding claims 8,9,11, a heat exchanger 42 is disposed in reservoir 41 (col. 4 lns 4-10) which is in series with the pump and the pad.

Regarding claims 12,13,39, a control system is said to control the rate of flow of liquid as well as the temperature of the fluid (col. 3 lns 1-3).

Regarding claim 28, see rejection of claim 1. The Copeland reference claims that the bladder 22 is formed of a flexible liquid impervious material 9 (col. 8 lns 57-61). The securing means 27 serves as an outer wrap adapted to compressively attach the pad to the user.

Regarding claim 33, see rejection of claims 1,8,9,11. Fig. 1 of Copeland shows a plurality of bladders.

Regarding claim 36, fluid flow in the bladder is aligned with the direction of lymph flow.

**Claims 1, 8-11, 33, 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Mason et al (US 5,080,089).**

Mason discloses a therapeutic pad comprising a bladder 1 with an inlet and outlet port, a fastener and a pump 21. A heating element that heats fluid in a reservoir is disposed in series with the pump and therapeutic pad that cools the liquid to a temperature between 32°F and 70°F (col. 3 lns 59-62, col. 4 lns 1-3). The water is heated as well (col. 4 lns 8-9).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 5-7, 21, 22, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copeland et al. or Mason et al. in view of Kelly et al (US 5,383,919).**

Kelly discloses a therapeutic pad comprising a plurality of spot welds 50 and seal lines 44 that are RF or heat welded (col. 4 lns 28-30) and serve as flow directing blockages. It would have been obvious to one of ordinary skill at the time the invention was made to modify either Copeland or Mason with flow directing means as taught by Kelly to such structures to cause “optimal fluid flow patterns within the...pad.” (col. 4 lns. 31-33, 38-40).

Regarding claim 21, the spot welds as taught by Kelly would inherently restrain the inner and outer panel from separating each other by more than 1 inch. In addition, the plurality of fasteners 27 are provided to prevent the bladder from excessive expansion. It would have been obvious to one of ordinary skill at the time the invention was made to prevent the expansion of the bladder by only one inch, for it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 29, Mason teaches an outer cushioning material 10 made of cloth or foam that can be bonded directly to the bladder. The bladder is made of elastomeric skin and therefore if the cover is bonded to the bladder then inherently the cover would also have to be elastic in order to maintain the quality of being elastic.

**Claims 12-15, 39, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mason in view of Copeland.**

Pressure regulator 72 of Copeland automatically controls the pressure in the system, or the rate of flow of the liquid to the pad. Mason teaches a bypass circuit in valve. The heat exchanger is bypassed when the valve is as in fig. 4 (col. 3 lns 33-46). It would have been obvious to modify Mason to include means to control the pressure and temperature of the device

as taught by Copeland in order to prevent the device from injuring the patient by applying too much pressure or temperature.

**Claims 16, 17, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copeland et al. or Mason et al. in view of Ruscigno (US 4,552,132).**

Regarding claim 16, Copeland and Mason lack pulsed liquid flow. Pulsed liquid delivery to a bladder is common in the art. Ruscigno discloses a therapeutic pad that comprises a heater as well as pulsed fluid delivery to a bladder (see abstract, col. 1 ln 69). It would have been obvious to one of ordinary skill at the time the invention was made to modify either Copeland or Mason to provide pulsed fluid delivery as taught by Ruscigno to promote local circulation and create muscle relaxation.

Regarding claim 17, the pulsed liquid flow has a duration that is equal to the transit time of itself, or the liquid flow through the bladder. Furthermore, the intensity and frequency of the pulsed fluid delivery can be adjusted (col. 3 lns. 33-36).

Regarding claim 23, the pulses taught by Ruscigno would create liquid pressure in the pad that will pulsate between a relatively high and relatively low pressure.

**Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mason et al. in view of Copeland et al. as applied to claim 39 above, and further in view of Ruscigno.**

It would have been obvious to one of ordinary skill at the time the invention was made to further modify Mason to provide pulsed fluid delivery as taught by Ruscigno to promote local circulation and create muscle relaxation.

**Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Copeland et al. in view of Kelly.**

Regarding claim 27, the therapeutic pads of Copeland would appear to extend a substantial portion of the leg. It would appear to comprehend the thigh region however, Copeland appears silent with regard to whether or not it extends to the thigh region. However, the examiner takes official notice that is commonplace in the art to apply therapy to the entire length of the leg including the thigh of a user. It would have been obvious to one of ordinary skill at the time the invention was made to provide the device of Copeland to the thigh of a user for it is well known in the art to apply therapy to any desired part of the body including the thigh region.

It would have been obvious to one of ordinary skill at the time the invention was made to modify Copeland with flow directing means as taught by Kelly to cause "optimal fluid flow patterns within the...pad." (col. 4 lns. 31-33, 38-40).

**Claims 24, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Copeland et al. or Mason et al. in view of Goldsmith (5,407,421).**

Goldsmith teaches a therapeutic pad that comprises a bladder that is filled with fluid that is a water and isopropyl alcohol mixture (col. 6 lns. 10-16). Although the reference is silent in regards to the actual proportions of the mixture, it would have been obvious to vary the proportions of the mixture to 80% water and 20% isopropyl alcohol since a change in proportion is generally recognized as being within the level of ordinary skill in the art. *In re Reese*, 129 USPQ 402. it would have been obvious to one of ordinary skill in the art to modify either Copeland or Mason to include isopropyl alcohol as taught by Goldsmith to prevent the water from freezing.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson, can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

27 July 2006

  
Danton DeMille  
Primary Examiner  
Art Unit 3764